

Notice of Allowability

Application No.

10/073,301

Examiner

DiBrino Marianne

Applicant(s)

REITER ET AL.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's amendment filed 6/27/05.
2. ☒ The allowed claim(s) is/are 63.
3. ☒ The drawings filed on 7/2/02 & 11/4/04 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>attached hereto</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

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DETAILED ACTION

1. The present application was filed containing a power of attorney to Mr. Sol Sheinbein and Mr. Martin Moynihan. A correspondence address was supplied for G.E. Ehrlich (1995) Ltd c/o Mr. Anthony Castorina. No address was supplied for Mr. Sol Sheinbein or Mr. Martin Moynihan except through G.E. Ehrlich c/o Mr. Castorina.

Mr. Sol Sheinbein was excluded from practice before the Patent and Trademark Office (Office). The Office does not communicate with attorneys or agents who have been suspended or excluded from practice.

As a correspondence address, other than to G. E. Ehrlich c/o Mr. Anthony Castorina, is not of record, this Office action is being mailed to the other practitioner of record at his/her last known address as listed on the register of patent attorneys and agents. To ensure that a copy of this Office action is received in a timely manner to allow for a timely reply, a copy of the Office action is being mailed directly to the address of the inventor first named in the declaration or oath. Any reply by applicant(s) should be by way of the remaining practitioner(s) of record and should include a new correspondence address.

2. Applicant's response filed 6/27/05 is acknowledged and has been entered.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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4. Claim 63 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 11, 13, 22, 23 and 24 of copending Application No. 10/371,942 (publication US 20030223994 A1) in view of admissions in the instant specification on page 52 at lines 7-23 and pages 53-61 and admitted prior art on page 52 at lines 15-23, page 53 at lines 1-6 and at the sentence spanning pages 2 and 3.

Claims 1, 2, 4, 11, 13, 22, 23 and 24 of copending Application No. 10/371,942 encompass an antibody that comprises a VH and an VL (claim 1) that is an scFv (claim 11, *i.e.*, the VH and VL are components of the same polypeptide chain) that is specific for a fragment of gp100 (claim 2) that is IMDQVPFSV (claim 4), said antibody does not bind either the MHC or the peptide in the absence of the MHC or the peptide (claim 1), and pharmaceutical composition thereof.

The said admissions in the specification are that the gp100 peptide G9-209M is IMDQVPFSV, that a scFv antibody with specificity of binding for the said gp100 peptide bound to HLA-A2.1 consists of the amino acid sequence of SEQ ID NO: 9 (recited in instant claim 63) and reacted only to the HLA-A2.1/peptide complex and not to either component or to complexes containing an irrelevant control peptide, and that the binding of the scFv antibody was very high affinity in the low nanomolar range ("wherein the association constant for binding of the protein to the complex is at least 10^7 M⁻¹" recited in claim 13 of copending Application No. 10/371,942).

The admitted prior art on page 52 at lines 15-23, page 53 at lines 1-6 and at the sentence spanning pages 2 and 3 is that the melanoma tumor cell gp100 peptide G9-209M is one of three major immunogenic epitopes, and that this peptide in a single chain construct with HLA-A2.1 was previously shown to be functional with respect to the ability to stimulate specific CTL lines and clones, and that antibodies that target cancer cells were genetically fused to powerful toxins originating from both plants and bacteria, thus generating molecules termed recombinant immunotoxins.

Claim 22 is included in this rejection because it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have formulated the scFv antibody that is SEQ ID NO: 9 in a pharmaceutically acceptable carrier, particularly the scFv antibody linked to a toxin, *i.e.*, the cytotoxin recited in claim 23 of copending Application No. 10/371,942, or linked to a label.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to more effectively treat cancer in keeping with the teaching of the admitted prior art.

The presently claimed protein comprising the amino acid sequence of SEQ ID NO: 9 is an embodiment of the protein recited in the said claims of copending Application No. 10/371,942.

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5. Given that a provisional double patenting rejection over copending USSN 10/371,942 would be the only rejection remaining in this application; such a provisional obvious double patenting is **WITHDRAWN** to permit this application to issue. See MPEP 804.

EXAMINER'S AMENDMENT

6. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this Examiner's Amendment was given by Mr. Martin Moynihan in an interview on 7/19/05 and 7/27/05 (Mr. Moynihan left a telephone message).

7. In claim 63:

a. "an" has been deleted after "comprising" and before "amino acid sequence" and ~~the~~—has been added after "comprising" and before "amino acid sequence" at line 1.

b. "as" has been deleted at line 1.

8. In the specification:

a. on page 31 at line 10, "http://" has been deleted from the hyperlink address at line 10 before "immuno.bme.nwu.edu".

b. on page 31 at line 10, "kabbat" has been deleted before "data base" and ~~Kabat~~—has been added before "data base".

c. on page 34 at line 8, "http://www." has been deleted from the hyperlink address after "interface at".

d. on page 37 at line 12, "http://www." has been deleted from the hyperlink address after "can be found in".

e. in the table spanning pages 38 and 39 **at the last column of each of rows 1-8**, "http://www." has been deleted.

f. on page 39 at line 4, "http://www." has been deleted after "website", and "http://" has been deleted after "data base", and "kabbat" has been deleted before "data base" and replaced with "Kabat".

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g. on page 40 at line 4, "hereinbelow" has been deleted and replaced with --herein below--.

h. on page 40 at line 11, "http://" has been deleted from the hyperlink address.

i. on page 48 at line 10, --d—has been added to the word "immunize" to be "immunized".

j. on page 52 at line 16, "a" has been deleted after "is one of" and "three major".

REASONS FOR ALLOWANCE

9. The following is an examiner's statement of reasons for allowance:

a. The Examiner has withdrawn the provisional obviousness-type double patenting rejection over copending USSN 10/371,942 as per MPEP 804 as enunciated above at item #4.

b. Claim 63 is pending and is allowable.

c. The claimed isolated protein comprising the amino acid sequence set forth in SEQ ID NO: 9 is not taught or suggested by the prior art.

d. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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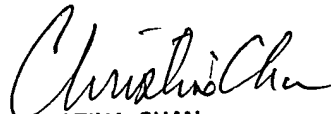
10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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July 29, 2005



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